UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JENNIFER L. HILLMAN and SURYA K. GOLI

Appeal No. 2004-1802
Application No. 09/848,915

ORDER UNDER 37 CFR § 41.50(d)

Before, WILLIAM F. SMITH, MILLS and GRIMES, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

ORDER UNDER 37 CFR § 41.50(d)

Background

The claimed subject matter relates to "nucleic acid and amino acid sequences of a novel tumorigenesis protein and to the use of these sequences in the diagnosis, prevention and treatment of disorders associated with cell proliferation and inflammation." Specification, page 1.

37 CFR § 41.50(d) Order

Under the provisions of 37 CFR § 41.50(d),[1] we require applicants to address the following matters:

We invite attention to Application No. 09/209,859 where, according to Patent and Trademark Office (PTO) records, applicants filed a Notice of Appeal from the examiner's final rejection on April 27, 2001.[2] After a briefing stage and oral hearing on February 21, 2003, another panel of the Board handed down its decision in the '859 application, affirming the examiner's final rejection of claims 1 and 11 (Appeal No. 2002-0774, BPAI 2003).

We think it clear that Appeal No. 2002-0774, in Application No. 09/209,859, bears close relationship to the instant appeal. In Appeal No. 2002-0774, the claims are drawn to a substantially purified polypeptide, viz., a transmembrane protein designated ONMO having the amino acid sequence shown in SEQ ID NO:1; as well as naturally occurring variants and biologically active fragments thereof, and pharmaceutical compositions comprising any of those polypeptides in conjunction with a pharmaceutical carrier. The sole issue presented was whether applicants' claims were supported by a disclosure of utility sufficient to satisfy 35 U.S.C. § 101.

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[1] As stated in 37 CFR § 41.50(d)(effective September 13, 2004), "[t]he Board may order appellant to additionally brief any matter that the Board considers to be of assistance in reaching a reasoned decision on the pending appeal. Appellant will be given a non-extendable time period within which to respond to such an order."

[2] The named inventors in the instant application are Jennifer L. Hillman, and Surya K. Goli. In Application No. 09/209,859, the inventors are Jennifer L. Hillman, Surya K. Goli, Olga Bandman, and Karl J. Guegler.

In what the previous panel referred to as "a second line of argument" or "a second line of reasoning," applicants argued that their claimed polypeptides have utility because all expressed human genes and polypeptides have utility as research tools (Application No. 09/209,859, Paper No. 28, page 9, lines 3 through 5; and paragraph bridging pages 10 and 11). Applicants reasoned that the technique of expression profiling, in which the expression of numerous genes is compared in two or more samples, is used in research relating to toxicology testing, drug development, and disease diagnosis; that "[g]enes or gene fragments known to be expressed, such as the invention at issue, are tools essential to any technology that uses expression profiling;" that "[t]he more genes that are available for use in toxicology testing, the more powerful the technique;" and that "there is no expressed gene which is irrelevant to screening for toxicological effects, and all expressed genes have a utility for toxicological screening. This is true for both polynucleotides and polypeptides encoded by them." Id., paragraph bridging pages 10 and 11.

Additionally, applicants argued before the previous merits panel that "[as] used in toxicology testing, drug discovery, and disease diagnosis, the claimed invention has a beneficial use in research other than studying the claimed invention . . . It is a tool, rather than an object, of research." According to applicants, this distinguished their case from reported cases like Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), and In re Kirk, 376 F.2d 936, 153 USPQ 48 (CCPA 1967), where "the only known use for the claimed invention [was] to be an object of further study." Id., page 11, first full paragraph. Applicants also argued that § 101 is satisfied by utilities that apply equally to all expressed human genes and proteins; the utility need not be

"particular" to the claimed invention. "Practical real-world uses are not limited to uses that are unique to an invention." According to applicants, "all isolated and purified naturally occurring polynucleotide and polypeptide sequences which are expressible . . . can be and are used in a real-world context as tools for toxicological testing, e.g., for drug discovery purposes." Id., page 12, second full paragraph.

The previous merits panel reviewed governing principles of law; addressed and rejected applicants' "second line of argument;" and concluded that "[a]ppellants' disclosure in this case does not provide a specific benefit in currently available form, and therefore lacks the substantial utility required by 35 U.S.C. § 101." Id., page 31, lines 2-4. Accordingly, the examiner's decision, rejecting claims 1 and 11 in Application No. 09/209,859, was affirmed.

Similar to the claims in Application No. 09/209,859, the claims in this appeal are drawn to an isolated polypeptide selected from the group consisting of a polypeptide comprising SEQ ID NO:1; a polypeptide comprising a naturally occurring amino acid sequence at least 90% identical to an amino acid sequence of SEQ ID NO:1; and an immunogenic fragment of a polypeptide having an amino acid sequence of SEQ ID NO:1. All of the appealed claims stand rejected under 35 U.S.C. § 101 "because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility" (Examiner's Answer, page 5).

The Appeal Brief in this appeal includes essentially the same "second line of argument" addressed by the previous merits panel in Appeal No. 2002-0774 (Appeal Brief received April 11, 2002, Paper No. 20). For example, applicants argue:

1) that the HTAP protein "has numerous practical beneficial uses in toxicology testing, drug development and the diagnosis of disease." Brief, page 13.

2) that, the "claimed polypeptide can be used in 2-D PAGE gels and western blots to perform drug toxicology testing." Brief, page 13.

On these facts, we require that applicants explain why we should address anew the "second line of argument" in this case. Respecting the issue raised by the "second line of argument," that same issue having been raised previously in Appeal No. 2002-0774, why would the previous panel's treatment of that issue not be dispositive here? In particular, why should the facts and arguments set forth in applicants' Appeal Brief lead to a different conclusion than that reached by another panel in Appeal No. 2002-0774 rejecting applicants' "second line of argument?" We note in passing that applicants did not request rehearing on the same record within two months from the date of the decision in Appeal No. 2002-0774. Rather, according to PTO records, applicants elected to have the matter reconsidered by the examiner on a different record. See 37 CFR § 41.50(b).

We note that the evidence of record in this appeal differs from that of 2002-0774, in that the examiner in this case has entered and responded to Appellants' declaratory evidence. However, the panel in 2002-0774 "assum[ed] arguendo that the use of polypeptides to monitor gene expression in research related to toxicology testing, drug development, and disease diagnosis was well-established as [of] the application's filing date." Application No. 09/209,859, Paper No. 28, page 14. The panel then went on to explain in detail why Appellants' "expression profiling" argument was unconvincing, even assuming it was supported by evidence. See id., pages 14-31. Since the Furness

Declaration in this case appears to be directed to providing evidence in support of the same "expression profiling" argument, the panel's analysis in 2002-0774 appears to be equally applicable to this case.

Conclusion

In conclusion, we require applicants to address the foregoing matters considers to be of assistance in reaching a reasoned decision on the pending appeal. 37 CFR § 41.50(d)(effective September 13, 2004). We caution, however, that this is not an invitation to expand on points raised in the Appeal Brief or to rehash arguments already set forth in the Appeal Brief. This is not an invitation to raise arguments or issues on appeal, or to collaterally attack the decision in Appeal No. 2003-1115. See 37 CFR § 41.37(c)(1)(vii)(2004) ("Any arguments or authorities not included in the brief or reply brief filed pursuant to § 41.41 will be refused consideration by the Board, unless good cause is shown"). Applicants' response should be confined to the matters outlined above.

Time Period For Response

A period of one month from the date of this order is set for applicants' response. This time is non-extendable.

Failure to respond in a timely manner will result in dismissal of the appeal.

37 CFR § 41.50(d)

William F. Smith
Administrative Patent Judge

Demetra J. Mills
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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